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HUI, SAN MING R

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 18

Application Number: 09/666,146
Filing Date: September 20, 2000
Appellant(s): RIETHMULLER-WINZEN ET AL.

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For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 5, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-13 and 28-31.

Claims 14-27 are withdrawn from consideration as not directed to the elected invention.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-13 and 28-31 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,663,145	ENGEL et al.	9-1997
5,658,884	HODGEN	8-1997

Nachigell et al., Chapter 41 in Danforth's Ostetrics and Gynecology, 1994, pages 757-769

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-13 and 28-31 are rejected under 35 U.S.C. 103(a). This rejection is set forth in prior Office Action, Paper No. 10.

(11) Response to Argument

The information disclosure statement (IDS) submitted on May 14, 2003 was filed after the mailing date of the Final office action on April 4, 2002. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Appellant's arguments in page 7 to 9 averring the cited prior art's failure to teach the specific dosing regimen as a short term induction treatment for a period of about 4-12 weeks are not convincing. As discussed in the previous office action mailed April 4,

2002, Hodgen et al. clearly provides the motivation to optimize the dose and/or regimen so that the desirable hypoestrogenic effects can be achieved (See Hodgen et al. col. 4, line 49-53). Hodgen et al. also teaches that the treatment period is up to 97 days (~13 weeks), which is close to the dosing frequency of the claims herein. Hodgen et al. also teaches the LHRH antagonists can be administered periodically (See Hodgen et al. col. 5, line 38). The optimization of a dosage regimen for an active is considered within the skill of the artisan, absent evidence to the contrary. Moreover, according to MPEP 2144.05 III, applicants can rebut a *prima facie* case of obviousness by showing the criticality of a claimed range. However, no such evidence is seen to be present in the case.

Applicant's remarks filed January 18, 2002 that oral contraceptives do not cure endometriosis have been considered but are not found persuasive as to the nonobviousness of the claimed invention because even though oral contraceptives are not known to cure endometriosis, they clearly are known to treat endometriosis. In point of fact, endometriosis is currently known to be incurable, which in this aspect, the examiner agrees with the applicant. Therefore, combining oral contraceptives and LHRH antagonists, which are known to be useful to treat endometriosis individually into a single method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Additionally, no unexpected curative treatment effect for the claimed regimen over the cited prior art has been demonstrated. Further, the instant claims are not limited to a cure for diseases herein.

Appellants arguments in page 9 averring oral contraceptives do not cure endometriosis, and therefore, not obvious to be employed in the instant method are not convincing. Even though oral contraceptives are not known to cure endometriosis, they clearly are known to treat endometriosis. In point of fact, endometriosis is currently known to be incurable, which in this aspect, the examiner agrees with the appellant. Therefore, combining oral contraceptives and LHRH antagonists, which are known to be useful to treat endometriosis individually into a single method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Additionally, no unexpected curative treatment effect for the claimed regimen over the cited prior art has been demonstrated. Further, the instant claims are not limited to a cure for diseases herein.

Appellant's arguments in page 9-11 averring no motivation being provided by the cited prior art to combine various agents in treating ehdometiral hyperplasia are not convincing. The herein claimed agents are known to be useful in treating endometrosis individually. It flows logically to combine these agents into a single composition and use it for the purpose of treating the very same condition (See See *In re Kerkhoven* 205 USPQ 1069). Appellant further argues that "combining pharmaceutical agents can not be done freely" (quoting from page 10 of, second paragraph). The arguments are not convincing. As discussed in the previous office action, in contrary to applicant's assertion, it is well-known and routinely practiced in the pharmaceutical art to combine agents, which are known to be useful for the same purpose or condition individually, to treat the same medical condition. For example, Bactrim DS® is an antibiotic product

that contains two antibiotics in one product. Moreover, it is known in the art that two or three agents may be administered together or separately to manage hypertension; for example, β-blockers plus diuretics or ACE inhibitors plus diuretics plus calcium channel blockers. Furthermore, this is the same for managing diabetes: metformin and sulfonylurea are known to be useful together in the diabetic treatment regimen. Further the law presumes that agents known for the same purpose individually are useful in a combination for the very same purpose (See *In re Kerkhoven supra*).

Appellant also argues unconvincingly that Hodgen does not provide motivation to specifically adjust or optimize the dosing regimen to 4-12 weeks. As discussed above, Hodgen et al. clearly provides the motivation to optimize the dose and/or regimen so that the desirable hypoestrogenic effects can be achieved (See Hodgen et al. col. 4, line 49-53). Hodgen et al. also teaches that the treatment period is up to 97 days (~13 weeks) (in Table 1), which is close to the dosing frequency of the claims herein. Hodgen et al. also teaches the LHRH antagonists can be administered periodically (See Hodgen et al. col. 5, line 38). Appellant argues in page 11, last paragraph that examiner incorrectly analyzed the experimental data in view of Hodgen's teachings: "utilty of tittering individualized GnRH ant[sic] doses to amenorrhea, while maintaining tonic overian estradiol secretion in a milieu suitable for extended therapeutic regimens". The arguments are not convincing. Hodgen clearly teaches the regimens can be adjusted depending on the desirable hypoestrogenic effects, thereby treating various conditions and severity in different individuals. It is not clear where in Hodgen teaches the treatment period has to be 6 months or more. It is known that the dosage regimen is

clearly depend on the conditions, severity, sometimes weights of the patients, liver or kidney functions of the patients, concurrent medications and diseases the patients have. Hodgen clearly provides the motivation to optimize the dosing regimen (See Hodgen et al. col. 4, line 49-53).

Appellant also argues unconvincingly in page 12 the instant method does not require tittering of the dosage of LH-RH antagonists. Examiner notes that the instant method does not exclude tittering of the dosage so that the estrogen level will be maintained at below 40pg/ml (See Hodgen col. 8, line 63-64).

Appellant's arguments in page 12-23, which are the same as that in page 7-11, have been addressed above.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

San-ming Hui Patent Examiner AU 1617
July 18, 2003

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